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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,284	03/23/2001	Stephen Paul Bartels	P02930	7529

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BAUSCH & LOMB, INC.
ONE BAUSCH & LOMB PLACE
ROCHESTER, NY 14604-2701

EXAMINER
JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/03/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/816,284	BARTELS ET AL.	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 21 recites a composition in the form of tablets that is administered to humans *or other mammals*. The specification describes each ingredient with regard to the RDA for that ingredient. These RDA value are drawn to allowances for human beings. The specification fails to teach RDA's for each ingredient for any other mammal. Therefore, the RDA's for other mammals were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)), the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior

art; (f) the predictability of the prior art; (g) the breadth of the claims; and (h) the relative skill in the art.

(a) In order to utilize the system as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. An undetermined number of experimental factors for determining the RDA of each ingredient for mammals other than humans would have to be resolved by the practitioner for the reasons discussed below.

(b & c) The specification states that objects of the invention include providing a dietary supplement for humans and other animals that strengthens and promotes retinal health. However, the specification lacks a reasonable level of guidance for a dietary supplement, and working and/or prophetic examples are clearly absent. Applicant has not taught or defined how the invention arrives at particular dosage levels for other mammals. There is no guidance as how to select the proper RDA for other mammals, such as the physical size, appropriate supplements for each mammal, metabolism of each mammal, bioavailability in each animal, nor any substantial teachings as to which ingredients of the supplement are suitable with each animal or mammal.

(d) The nature of providing a dietary supplement for mammals other than humans is complex.

(e & f) Although the art provides a certain level of guidance with regards to the specific ingredients used as treatment for eye disease and macular degeneration, these teachings do not provide sufficient guidance where the specification is lacking. The art

demonstrates that the particular ingredients are used to treat macular degeneration but treating mammals other than humans is clearly not predictable.

(g) The claims are broad because there is no guidance for the appropriate daily allowances of each ingredient for mammals other than humans.

(h) The level of skill of those in the art involving the determination of RDA for each ingredient for mammals other than humans is high.

The skilled practitioner would first turn to the instant specification for guidance in providing a dietary supplement to treat macular degeneration in mammals other than humans, as claimed. However, the specification does not provide sufficient guidance for providing a dietary supplement to treat macular degeneration in mammals other than humans, as claimed. As such, the skilled practitioner would turn to the prior art for such guidance. However, the prior art does not teach a dietary supplement to treat macular degeneration in mammals other than humans, as claimed. Finally, said practitioner would turn to trial and error experimentation to make/use a dietary supplement to treat macular degeneration in mammals other than humans, without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 recites that he blend of ingredients provides certain

dosage levels *up until an expiration date of said dosage form produced from said blend.* It is unclear what that expiration date is, how to determine what the date could be or from what point the expiration date is calculated. Therefore, Claim 14 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek (US 6103756) alone or in view of Newsome, D. A., Oral Zinc in Macular Degeneration, Arch. Ophthalmol., Vol. 106, February 1988, pp. 192-198.

Gorsek teaches a formulation for treating macular degeneration comprising vitamin C, vitamin A, vitamin E, zinc and copper (Col. 1, line 50 - Col. 4, line 18). It further teaches the incorporation of lutein and alpha lipoic acid (Col. 2, line 30 – Col. 3,

line 10). Vitamin C is present in the formulation in amounts of 100 to 6000 mg (Col. 1, line 50-67). Vitamin E is present in the formulation in amounts of 100 to 2000 IU (Col. 1, line 50-67). Vitamin A is present in the formulation in amounts of 100 to 20000 IU (Col. 1, line 50-67). Zinc is present in the formulation is amounts of 25 mg (Col. 2, line 30 – Col. 3, line 10). Copper is present in the formulation is amounts of 1 mg (Col. 2, line 30 – Col. 3, line 10). The amounts taught in Gorsek anticipate the claimed ranges for vitamin C, vitamin A, vitamin E and copper. Gorsek does teach that the amounts can be modified or changed to provide a unique desired product, which falls within the teachings of the reference.

Gorsek does not expressly teach that the amounts of zinc present are 4 to7 times the RDA for zinc.

The Newsome article teaches that administering 5.3 times the RDA for zinc to treat macular degeneration in humans.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a dietary supplement comprising vitamins A, E and C,

zinc and copper to treat macular degeneration is the recited amounts in the instant claims.

One of ordinary skill in the art would have been motivated to do this to provide a formulation that helps to protect the and neutralize free radicals that may damage vision in the body.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaHaye et al. (US 5075116) in view of Gorsek further in view of Newsome.

LaHaye teaches a formulation for treating macular degeneration comprising vitamin C, vitamin E, copper, zinc and vitamin A (Col. 4, lines 3-24; Col. 8, lines 33-26). Vitamin C is present in amounts up to 2g (Col. 4, line 58 – Col. 5, line 21). Vitamin E is present in the formulation in amounts up to 600 IU (Col. 5, lines 22-44). Zinc is present in amounts of approximately 100 mg (Col. 5, line 45 – Col. 6, line 22). Copper is present in amounts of 2-3 mg (Col. 6, lines 24-54). Vitamin A is also included in the formulation but no specific amount is given.

LaHaye does not expressly teach the amounts recited in the instant claims for zinc and vitamin A. LaHaye further does not teach the incorporation of lutein, zeaxanthine, a raw material combination, alpha-lipoic acid, phenolic compounds, or anthocyanosides.

As stated above, Gorsek teaches Vitamin is present in a composition for treating macular degeneration in amounts of 100 to 20000 IU (Gorsek, Col. 1, line 50-67).

Gorsek also further teaches the inclusion of lutein and alpha lipoic acid (Col. 2, line 30 – Col. 3, line 10).

As stated above, Newsome teaches that zinc can be present in a formulation treating macular degeneration is amount of about 5 times the RDA of zinc.

Again, while the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a formulation for treating macular degeneration comprising vitamins A, E, C, zinc and copper as well as lutein and alpha-lipoic acid in the amounts recited in the instant claims. Both Gorsek and LaHaye teach that vitamins A, E, C, zinc and copper are known to be incorporated into formulations treating macular degeneration. Both teach ranges for the concentration of each ingredient. Newsome teaches the proper range for the inclusion of zinc. All formulations treat macular degeneration

One of ordinary skill in the art would have been motivated to do this to provide a formulation for scavenging free radicals and other oxidants associated with eye disease.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday through Friday 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
June 27, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600